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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,262	07/09/2003	Ryuichi Morishita	Q75926	5695

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EXAMINER	
KELLY, ROBERT M	
ART UNIT	PAPER NUMBER
1633	
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03/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/615,262	MORISHITA ET AL.	
	Examiner	Art Unit	
	ROBERT M. KELLY	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 December 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *Web page definition of peripherial vacular disease*.

DETAILED ACTION

Applicant's response of 12/12/07 is entered.

No claim amendments have been made.

Claims 7-11 are presently pending and considered.

Specification

In light of the amendment to the abstract, the objection to the specification is withdrawn.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 7-11 remain rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6,936,594. Although the

conflicting claims are not identical, they are not patentably distinct from each other because the differences are that the present claims are not drawn to treating cerebral vascular disorders (Claims 1-3 of 6,936,594) or injection into the subacrachnoid space (Claim 2 of 6,936,594), for reasons of record. However, the other patent claims are drawn to HVJ-liposomes, which are sendai viral vectors fused to liposomes, and therefore are viral vectors which are modified, and also meet the limitations of present claims 8-10.

It is noted for the record that the Examiner is at a loss as to whether HVJ-liposomes should be classified as viral or non-viral, as they appear to be both, being a vector placed in a liposome and fused with the viral vector envelope of a Sendai viral vector. Hence, the simple distinguishing features of present claim 11 still appears to be encompassed.

However, the present patent teaches treating the cerebrum (e.g., p. 10, last paragraph), which teaches brain and the objective site. And hence, the objective site of the brain encompasses the subarachnoid space, as if such site is suffering from lack of circulation, it would be the site to treat.

Hence, it would have been obvious to treat the brain for insufficient circulation given the teachings and claims of 6,936,594, and the Artisan would have have been motivated to do so, as the specification and claims of such patent teaches such treatments, with similar vectors. Moreover, the Artisan would have had a reasonable expectation of success, as the patent teaches such.

Response to Argument – Double Patenting, 6,936,594

Applicant's argument has been fully considered but is not found persuasive.

Applicant argues, utilizing a declaration of Dr. Morishita, that the patent is drawn to treating the central nervous system, which is distinct from the periphery, and hence, the claims do not encompass the same subject matter, further citing Steadman's Medical dictionary, pages 250, and 1463 to provide support for the difference between the peripheral and central nervous system (p. 4).

Such is not persuasive. While Dr. Morishita is correct to state that "peripheral" is that which is not "central", with respect to the limitations of the claims, the peripheral circulation is what is encompassed, not that of peripheral nervous tissue. It is well known in the Art that the peripheral circulation is that circulation which is not the cardiac circulation. Hence, Applicant's argument, and that of Dr. Morishita, appear to be incorrect, analyzing something completely distinct from what is claimed by Applicant. To wit, MedicineNet.com provides the attached definition of peripheral vascular disease, which teaches that peripheral circulation is taken with respect to that which is not the cardiac circulation.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002

do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 7-9 and 11 remain rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,121,246 to Isner.

With regard to Claim 7, Isner teaches inducing new blood vessel formation in ischemic muscle tissue by direct injection of a DNA encoding, *inter alia*, hepatocyte growth factor, to thereby induce new blood vessel formation, and obtain substantial improvements in blood flow (e.g., Claims 1, 14, 16, and 29). Moreover, the purpose of these methods includes treating insufficiency of blood flow causing ischemia, which may be caused by *inter alia*, diffuse vascular peripheral disease (e.g., col. 2, paragraph 2).

With regard to Claim 8, 9, and 11, Isner teaches non-viral vectors, encapsulated in liposomes, as well as adenoviral vectors (e.g., col. 3, paragraph 2).

Response to Argument – anticipation, Isner

Applicant's argument of 12/12/07 has been fully considered but is not found persuasive.

Applicant argues, through another declaration by Dr. Morishita, that while Isner teaches HGF, that Isner demosntrates VEGF, that from such, due to the distinct actions of HGF and VEGF, the Artisan would not predict it to work. Still further, it is argued that nothing about gene therapy is taught by Isner, and while bFGF was known to work, the Artisan would not have reasonably expected it to work in gene therapy. Lastly, Applicant argues that Isner is unique and complicated, comprising insertion of a catheter having hydrophilic polymers containing the

VEGF gene attached to the end, hence, it is entirely distinct from administration to the injured tissue or muscle (pp. 5-6).

Such is not persuasive. First, HGF is in the claims, not just in the specification of Isner. Hence, it is presumed valid, regardless of argument otherwise. Second, with regard to gene therapy, Isner's claims also teach such, and hence, it is again presumed valid. Lastly, with regard to Isner's complicated methods, such are limited to the examples, not the claims, which are drawn to the same direct administration, and hence, is presumed valid.

Note: Claim 10

It is noted that no rejection was made based on Isner, to Claim 10, drawn to the HVJ-liposome compositions. Such is because Applicant provides the earliest art to such vectors, as evidenced by Applicant's priority, and further, the double-patenting rejection to similar methods with HVJ-liposomes. Hence, the art rejection is not proper for Claim 10.

Conclusion

No Claim is allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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